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Randomized controlled trial comparing the impact of supplementary feeding with either ready-to-use therapeutic food or corn-soy blend among malnourished anti-retroviral therapy clients in Malawi

Submission date
24/01/2006

Registration date
12/05/2006

Last Edited
02/06/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

P.04/05/350

Study information

Scientific Title

Study objectives
Among wasted human immunodeficiency virus (HIV)-infected adults starting anti-retroviral therapy (ART), those that receive short-term, nutrient-dense ready-to-use therapeutic food (RUTF), may show an increase in body weight, experience fewer significant clinical events and higher CD4 counts, than their counterparts that receive corn-soy blend (CSB)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malawi College of Medicine Research Ethics Committee (COMREC), reference number: P.04/05/350; Federal Wide Assurance Number 00001395 and registration number 00001157. Also reviewed and approved by the Human Studies Committee, Washington University School of Medicine, St. Louis, Missouri.

Study design
Randomized single-blind (investigator) controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malnutrition and HIV infection

Interventions
375 g CSB (300 g corn and 75 g soy flour fortified with vitamins and minerals), or 260 g peanut-based RUTF (26% dried skimmed milk, 27% sugar, 26% peanut paste, 20% vegetable oil, and 1.5% vitamins) and mineral premix per person per day during their first three months of ART

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ready-to-use therapeutic food or corn-soy blend

Primary outcome(s)

Body mass index and fat free body mass as measured by the bioelectrical impedance at 3, 6, 9 and 12 months

Key secondary outcome(s))
1. The number and severity of clinical events at 3, 6, 9 and 12 months
2. Monthly change in quality of life assessment
3. The change from baseline in the CD4 count at three months
4. Serum albumin and hematocrit at three months
5. Viral load at three months
6. Compliance with ART regimen
7. Cost-effectiveness of the two dietary regimens

Completion date
06/05/2007

Eligibility

Key inclusion criteria
1. Adults (>18 years old) diagnosed with acquired immune deficiency syndrome (AIDS) and meeting eligibility criteria for ART according to the National HIV treatment guidelines
2. World Health Organisation (WHO) stage III or IV or any WHO stage and a CD4 count <200 /mm^3 and beginning treatment with ART with a body mass index (BMI) of <18.5

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age <18 years
2. Pregnant or lactating women
3. Enrolment in any other supplementary feeding program

Date of first enrolment
06/01/2006

Date of final enrolment
06/05/2007

Locations

Countries of recruitment
Malawi

United States of America

Study participating centre
Washington University in St. Louis School of Medicine
Missouri
United States of America
63110

Sponsor information

Organisation
St. Louis Children's Hospital (USA)

ROR
https://ror.org/00qw1qw03

Funder(s)

Funder type
Charity

Funder Name
Academy for Educational Development, Washington DC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	22/05/2009	Yes	No